PATENT
144002-2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Douglas T. DIETERICH

Serial No.: 09/862,404

Filing Date: May 21, 2001

For: **METHOD OF TREATING ANEMIA CAUSED BY RIBAVIRIN TREATMENT OF HEPATITIS C USING ERYTHROPOIETIN ALPHA**

Examiner: Canella, K.

Art Unit: 1642

745 Fifth Avenue, New York, NY 10151

EXPEDITED PROCEDURE
RESPONSE AFTER FINAL
UNDER 37 C.F.R. 1.116

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Date of Deposit: April 7, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

CHARLES JACKSON
(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)

DECLARATION OF DOUGLAS T. DIETERICH UNDER 37 C.F.R. §1.131

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Dear Sir:

Douglas T. Dieterich declares and states that:

1. I am the inventor on the above application ("the present application"), am familiar with it and its prosecution, and understand that Bruchfeld *et al.* ("Management of ribavirin treatment in renal insufficiency and dialysis," September 2000, Journal of the American Society of Nephrology, Vol. 11, Program and Abstract Issue, page 57) ("Bruchfeld") has been cited. This Declaration is to show that the subject matter of the present invention was conceived and

reduced to practice in the United States prior to the Bruchfeld September 2000 publication date.

2. The conception and reduction to practice of the subject matter of the present application is evidenced, in part, by the present application itself, especially the Examples presented therein. For instance, attention is respectfully directed to the May 21, 2001 filing date of the present application, and Example 3 of the present application that describes a forty-week study carried out according to the present invention, which is directed to a method for treating hepatitis C in an HIV-negative patient in need thereof comprising administering ribavirin (RBV) or RBV and interferon-alpha (IFN), wherein the improvement comprises administering Erythropoietin (EPO) concomitantly or sequentially or via co-administration with the RBV or with the RBV and IFN and the RBV is administered at a maximum effective of dosage 800 to 1200 mg per day, or treating RBV or RBV and IFN induced anemia in hepatitis C patients comprising administering EPO to a patient in need thereof, wherein the RBV or RBV and IFN induced anemia is a result of treating said hepatitis C patients with a maximum RBV effective dosage of dosage 800 to 1200 mg per day.

3. I hereby confirm that the work reported in Example 3 was performed in the United States prior to the filing date of the May 21, 2001 present application. Given the May 21, 2001 filing date of the present application, and given that the study of Example 3 had been completed in the United States prior to the filing date, I hereby confirm that an embodiment of the invention was indeed conceived and reduced to practice in the United States prior to the September 2000 date of Bruchfeld. Accordingly, I am advised and therefore believe that the present application is entitled to antedate Bruchfeld within the purview of 37 C.F.R. §1.131. And I respectfully request that Bruchfeld be considered antedated and not available as prior art against the present application.

4. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 4/6/04

Douglas T. Dieterich, M.D.